

JUN 23 2008

PATENT APPLN. NO. 10/562,059
RESPONSE UNDER 37 C.F.R. §1.111

PATENT
NON-FINAL

REMARKS

For convenience, the headings used in the Action will be used in the present response.

Claim Objections

The Office is objecting to claims 17 to 20 as reciting grammatically incorrect terminology. Claims 17-20 have been canceled. The objection is now moot.

Claim Rejections - 35 USC § 112

Claims 1 to 20 are rejected under 35 U.S.C. §112, first paragraph. The position of the Office as explained in the rejection is that the specification, while being enabling for specific asparagine-linked disialoundecaoligosaccharide-fatty acid amides disclosed in the specification, does not reasonably provide enablement for all asparagine-linked disialoundecaoligosaccharide-fatty acid amides.

The claims have been amended to limit the asparagine-linked disialoundecaoligosaccharide-fatty acid amide of the invention to one where the fatty acid contains 8 to 24 carbon atoms. Specifically, claim 1 has been canceled and claim 2 has been rewritten in independent form. Claim 8 has also been amended to limit the disialoundecaoligosaccharide-fatty acid amide of the drug

recited therein to one in which the fatty acid has 8 to 24 carbon atoms.

Applicants respectfully submit that a person of ordinary skill in the art could make and use an asparagine-linked disialoundecaoligosaccharide-fatty acid amide, where the fatty acid has 8 to 24 carbon atoms, and a drug containing the asparagine-linked disialoundecaoligosaccharide-fatty acid amide or containing the asparagine-linked disialoundecaoligosaccharide-fatty acid amide and asparagine-linked disialoundecaoligosaccharide (as recited in claim 8) without undue experimentation. Notwithstanding that the asparagine-linked disialoundecaoligosaccharide portion of the molecule includes an oligosaccharide of 11 units, straight or branched, in view of the limitation of the fatty acid of the fatty acid amide to one having 8 to 24 carbon atoms, it is believed that only routine experimentation would be required to make a asparagine-linked disialoundecaoligosaccharide-fatty acid amide within the scope of the claims and that the amount of experimentation to use the disialoundecaoligosaccharide-fatty acid amide would not be unduly extensive.

Claims 9, 10, and 17 to 20 are rejected under 35 U.S.C. §112, first paragraph, for the stated reason that the specification, while being enabling for a drug for treating influenza virus

infection, does not reasonably provide enablement for a drug for preventing and/or curing viral infections.

Claims 9, 10, and 17 to 20 have been canceled. This rejection is now moot.

Claim Rejections - 35 USC § 102 & 35 USC § 103

Claims 1 to 5, 7 to 13, and 17 to 20 are rejected under 35 U.S.C. §102(b) as being anticipated by Michel et al. "Model Gycoconjugates consisting of biantennary N-glycans coupled to fatty acids: Synthesis and X-ray diffraction study" *Makromol. Chem.* (1985) Vol. 186, (hereinafter "Michel"). The Office identifies Michel as disclosing a coupling of sialoglycopeptides to fatty acids. More particularly, the Office states that in Michel a glycopeptide comprising a biantennary disialo-undecaoligosaccharide linked to asparagine was isolated and coupled to palmitic acid, which is a 16-carbon straight-chain saturated fatty acid. This conjugate is alleged by the Office to be an "asparagine-linked disialoundecaoligosaccharide according to the claims, and is reasonably considered to have the utility disclosed in the instant claims for treating influenza. Furthermore, the Office notes that the compound is dissolved in DMSO, which is reasonably considered to be a pharmaceutical additive.

Claims 6 and 14 to 16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Michel in view of Remington: The Science and Practice of Pharmacy, Twentieth Edition (hereinafter "Remington"). The Office notes that Michel does not disclose a composition further comprising any of the additive recited in instant claims 6 and 14 to 16. However, the Office cites Remington as disclosing glycerin as a pharmaceutical solvent and lactose, mannitol, glucose, and sucrose as diluents or binders for pharmaceutical tablets and takes the position that would have been obvious to one of ordinary skill in the art at the time of the invention to add any of the additives disclosed by Remington to the compounds discussed by Michel.

Michel discloses on page 2367, 3rd paragraph, that:

"The glycan part contains 87% of 2 → 6 and 13% of 2 → 3 linked N-acetylneuraminic acids as determined by methylation and mass spectrometry. The peptide part contains, for 1 mol of asparagine, 0.3 mol of glycine, 0.25 mol of glutamate, 0.2 mol of serine and traces of alanine and proline. It means that each glycopeptide molecule contains, on the average, about one amino acid residue in addition to asparagine at the glycosylation site."

From the above it is seen that, in Michel, a plural of amino acid residues are bonded to the oligosaccharide. Whereas, in the present invention, only Asn (asparagine residue) is bonded to the oligosaccharide. Thus, the present invention differs from Michel in the structure of the glycopeptide. This difference in the structure causes different characteristics in micell or cluster formation.

Attached hereto is a copy of *Biosci. Biotechnol. Biochem.*, 69(1), 166-178, 2005. This document relates to design and facile synthesis of neoglycolipids as lactosylceramide mimetics and their transformation into glycoliposomes, and describes, for example, on page 175, Figs 4 and 5, that characteristics such as inclusion ability of glycoliposomes, binding assay, etc., differ depending on the difference in the structure revealed in the bonding part, namely between DPPA and DPPE.

Accordingly, the above difference between the inclusion of a plural of amino acid residues and only an Asn residue in the structure of the glycopeptide causes unobvious differences in characteristics. Thus, the present invention is not anticipated by Michel, and is not obvious over a combination of Michel and Remington.

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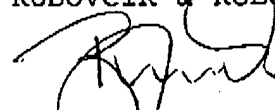
Removal of the 35 U.S.C. 102(b) and 35 U.S.C. 103(a) rejections of the claims is believed to be in order and is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated December 21, 2008, and is believed to place this application in condition for allowance.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,
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Attachment: Biosci. Biotechnol. Biochem., 69(1), 166-178, 2005